

Decision Memo for Hepatitis Panel/Acute Hepatitis Panel (Addition of ICD-9-CM 790.5, Other nonspecific abnormal serum enzyme levels, as a covered indication) (CAG-00335N)

Decision Summary

CMS has determined that ICD-9-CM diagnosis code 790.5, Other nonspecific abnormal serum enzyme levels, does not flow from the existing narrative for conditions for which a Hepatitis Panel/Acute Hepatitis Panel of tests is reasonable and necessary. Consequently, ICD-9-CM code, 790.5 shall remain on the list of "ICD-9-CM Codes That Do Not Support Medical Necessity." Tests on this list may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

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Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, Section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

TO: Administrative File: CAG – 00335N Addition of ICD-9-CM 790.5, Other nonspecific abnormal serum enzyme levels, as a covered indication for the Hepatitis Panel/Acute Hepatitis Panel National Coverage Determination (NCD).

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SUBJECT: Addition of ICD-9-CM 790.5, Other nonspecific abnormal serum enzyme levels, as a Covered Indication for the Hepatitis Panel/Acute Hepatitis Panel National Coverage Determination (NCD).

DATE: October 3, 2006

I. Decision

CMS has determined that ICD-9-CM diagnosis code 790.5, Other nonspecific abnormal serum enzyme levels, does not flow from the existing narrative for conditions for which a Hepatitis Panel/Acute Hepatitis Panel of tests is reasonable and necessary. Consequently, ICD-9-CM code, 790.5 shall remain on the list of "ICD-9-CM Codes That Do Not Support Medical Necessity." Tests on this list may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

II. Background

On July 24, 2006, CMS formally accepted a request for consideration to add ICD-9-CM code 790.5 to the covered indication code list for the Hepatitis Panel/Acute Hepatitis Panel NCD. This panel of tests is used for differential diagnosis in a patient with symptoms of liver disease or injury. Viral hepatitis infection may be detected when there are abnormal liver test results, with or without clinical signs or symptoms of hepatitis.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM Codes Covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM Codes Denied,” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM Codes That Do Not Support Medical Necessity,” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

IV. Timeline of Recent Activities

On July 24, 2006, CMS opened a coding analysis item regarding the addition of ICD-9-CM 790.5, Other nonspecific abnormal serum enzyme levels, as a covered indication for the Hepatitis Panel/Acute Hepatitis Panel National Coverage Determination (NCD). We posted a tracking sheet to the Internet (<http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=173>) and solicited public comment for 30 days on the appropriateness of adding code 790.5 to the list of covered codes for the Hepatitis Panel/Acute Hepatitis Panel NCD.

We did not receive any comments during the comment period, which ended August 23, 2006.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

On February 25, 2005, we announced in a final notice in the Federal Register (70 FR 9355) that we would maintain the accuracy of the coding lists without substantive changes to the narrative policy through an abbreviated process that did not require scientific evidence. We call this abbreviated process the Coding Analysis for Laboratories (CAL).

VI. CMS Analysis

The "ICD-9-CM Codes Covered by Medicare" list is intended to contain only those codes that flow from the narrative of the indication in the NCD. The Hepatitis Panel/Acute Hepatitis Panel NCD narrative includes the following indications:

1. To detect viral hepatitis infection when there are abnormal liver function test results, with or without symptoms of hepatitis.
2. Prior to and subsequent to liver transplantation.

The ICD-9-CM lists amylase, lipase, acid phosphatase and alkaline phosphatase as the nonspecific abnormal serum enzymes for ICD-9-CM code 790.5, Other nonspecific abnormal serum enzyme levels. Amylase and lipase are intracellular enzymes that are characteristically elevated in association with damage to the pancreas, not the liver. Acid phosphatase is useful in the diagnosis and staging of carcinoma of the prostate and is not used to identify damage to the liver. Alkaline phosphatase activity originates from the liver and bone. Alkaline phosphatase is an intracellular enzyme that is elevated in association with biliary tract obstruction. Though serum alkaline phosphatase elevation may provide a nonspecific indication of liver disease, it does not appear to have a role in the diagnosis of viral hepatitis. In contrast to characteristic high elevations of aspartate aminotransferase (AST) and alanine aminotransferase (ALT), alkaline phosphatase elevation is mild or absent in viral hepatitis.

The 790-796 series of the ICD-9-CM refers to "Nonspecific Abnormal Findings." The current list "ICD-9-CM Codes Covered by Medicare" in the Hepatitis Panel NCD includes only two codes in this series, 794.8, Abnormal liver scan, and 790.4, Nonspecific elevation of levels of transaminase or lactic acid dehydrogenase. In the CAL that added 790.4 to the list "ICD-9-CM Codes Covered by Medicare" we noted the following: "Characteristically, viral hepatitis causes high elevations of the levels of transaminases and LDH."

In summary, we have determined that ICD-9-CM code 790.5 does not flow from the narrative of the Hepatitis Panel NCD. This code describes a number of non-specific enzyme tests that are not reliably elevated with viral hepatitis infection. ICD-9-CM code 790.5 will remain on the list of "ICD-9-CM Codes That Do Not Support Medical Necessity." Tests in this list may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary by the local Medicare contractor.

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Bibliography

Widmann's Clinical Interpretation of Laboratory Tests, Eleventh Edition. Sacher RA, McPherson RA eds. F.A. Davis Company, Philadelphia, 2000.

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